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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,653	01/17/2002	David Henry Small	009621-39189	8742

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EXAMINER

KOLKER, DANIEL E

ART UNIT PAPER NUMBER

1649

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/051,653		SMALL ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Daniel Kolker		1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 8/22/05.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. Applicant's remarks and amendments filed 22 August 2005 have been entered. Claims 4 – 8 are canceled; claims 1 – 3 are pending and under examination.
2. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Rejections***

4. The following rejections made in the previous office action are withdrawn in light of applicant's amendments:

The rejection of claims 1 – 3 under 35 USC 112, first paragraph.

The rejection of claims 1 – 4 under 35 USC 103 as being obvious over Saez-Valero, and being obvious over Small, and being obvious over Szumanska. All three papers teach increased binding of proteins to the WGA, whereas the amended claims require decreased binding.

The rejection of claims 1 – 3 under 35 USC 103 as being obvious over DeGasperi and Savage, as DeGasperi is not drawn to diagnosis of Alzheimer's disease.

The double-patenting rejection over 6,461,831 is withdrawn due to applicant's amendment requiring decreased binding to WGA in patient's with Alzheimer's disease.

The double-patenting rejection over 10/648,548; the relevant claims have been cancelled and the new claims do not require determination of binding to WGA. Furthermore the specification of '548 indicates that more protein binds to WGA in AD patients than in controls (see p. 8 and 21 of '548) whereas the amended claims require decreased binding.

### ***Rejections Necessitated by Amendment***

#### ***Claim Rejections - 35 USC § 103***

5. Claims 1 – 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yao (1998. Journal of Neuroscience 18:2399 – 2411) and Sigma catalog (1994. pp. 1799 – 1801 and 1824 – 1825).

Yao teaches a method of detecting proteins from the brains of patients with Alzheimer's disease, wherein GlcNAc-labeling of a 160 kDa protein is significantly lower in patients with

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Alzheimer's disease as compared to normal controls. Yao's method included preparing crude brain extracts from human patients, all of whom died less than 19 hours before brain removal (see tables 1 and 2). The tissues were immediately frozen after removal (see p. 2400, bottom of first column) and thus are presumed to contain cerebrospinal fluid. Yao teaches isolation of protein (p. 2400, see "Preparation of brain extracts") and detecting the amount of galactosyltransferase-labeled protein in the extracts. Yao teaches that certain proteins, including a 160-kDa protein, show less labeling in the samples from patients with Alzheimer's disease (see Figure 2 and 5). Yao's method used radioactively-tagged galactose and Yao does not teach using labeled wheat germ agglutinin for detection of the glycosyltransferase-labeled proteins.

Sigma catalog pp. 1824 – 1825 indicates that WGA was available conjugated to labels (FITC product #L4895, TRITC L5266, biotin L5142, ferritin L1263, peroxidase L3892, L7017, L0390, Evans Blue L9884, 10nm colloidal gold L1894) and to sepharose (L6257). Sigma catalog (p. 1799) teaches that the reagent to which a lectin is conjugated does not alter the specificity of the lectin and further teaches that WGA binds specifically to glcNAc residues in proteins (see p. 1801, entry for *Triticum vulgaris* and p. 1824, which indicates that *Triticum vulgaris* is the source of WGA). It would have been obvious for one of ordinary skill in the art to use biotin-labeled WGA in the method of Yao with a reasonable expectation of success. A motivation for using WGA in the method of Yao would be obviate the need to use radioactivity. An artisan of ordinary skill would be motivated to use the labeled WGA to decrease exposure to radioactivity. The artisan would also find it reasonable to expect success, as Sigma teaches that lectins are suitable for studies of normal and pathological conditions, i.e. diagnosis (see p. 1799).

Applicant argues, on pp. 6 – 7 of the remarks filed 22 August 2005, that the instantly claimed method is advantageous and non-obvious over the art of record. The examiner notes that the newly-applied reference by Yao teaches a method that is only slightly different from the claimed method. The method from Yao also does not require purification of a specific protein from the sample, but rather is performed on crude protein extracts. As explained above, the modifications of Yao that applicant is claiming would have been obvious to one of ordinary skill in the art.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yao and Sigma as applied to claims 1 and 2 above, and further in view of Savage et al (1992. Avidin-Biotin

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Chemistry: A Handbook. Rockford, Illinois: Pierce Chemical Company, cited in previous office action). Sigma catalog teaches that biotin-labeled WGA was on sale in 1994 (see product L 5142, p. 1825) but neither Sigma nor Yao teach use of biotin-labeled WGA. It would have been obvious for one of ordinary skill in the art to use biotin-labeled WGA in the method of Yao et al. with a reasonable expectation of success. A motivation for using a biotin based system in a lectin-detection method is provided by Savage et al. in the paragraph spanning pp. 130 – 131: this system has an increased sensitivity and does not alter the binding properties of the lectin.

### ***Conclusion***

7. No claim is allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.

September 28, 2005

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER